APR 2 1 2005

K050576

510(k) SUMMARY

Safety and Effectiveness

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92."

Microalbumin TIA/ mAlb Calibrator Set 200/ mAlb Control-L, Control-H

Submitter

Name,	Good Biotech Corp.
Address,	38 34th Rd. Taichung Industrial Park Taichung City 407 Taiwan
Telephone number,	+886-4-23596873
Contact person,	Victor Chiou
Preparation date	February 18, 2005

Device

Trade name,	Microalbumin TIA Reagent mAlb Calibrator Set 200 mAlb Control-L, Control-H
Common name,	Urinary albumin immunological diagnostic assay Albumin calibrator Albumin control
Classification name	Albumin immunological test system (21 CFR § 866.5040) Calibrator (21 CFR § 862.1150) Quality control material (assayed and unassayed) (21 CFR § 862.1660)

Predicate Device

Trade name,	Randox Microalbumin Test kit Wako Micro-Albumin B/ Wako Micro Albumin Calibrator
510(k) number	K002674 K944664

Description

Good Biotech Corp. Microalbumin TIA is a ready to use reagent for the quantitative determination of low level albumin in human urine by turbidimetric immunoassay (TIA). When microalbumin of the urine sample encounters with duck anti-albumin antibody, the agglutination based on the antigen-antibody reaction increases the turbidity of the sample. The value of the absorbance change at 340 nm is proportional to the albumin concentration of the sample and is recorded by a general chemistry autoanalyzer. Then, the actual microalbumin concentration of the urine sample is determined by interpolation of the calibration curve obtained by standard samples with known albumin concentrations.

Intended Use

Reagent:
Good Biotech Corp. (GBC) Microalbumin TIA system is intended to be used for the quantitative determination of low level albumin in human urine by turbidimetric immunoassay (TIA). Measurement of albumin aids in the diagnosis of kidney disease.

Calibrator:
GBC mAlb Calibrator Set 200 is intended to be used with GBC Microalbumin TIA for the quantitative determination of microalbumin in urine samples.

Control:
GBC Microalbumin Controls are intended to be used as the assayed quality control material for the urinary albumin analysis.

For In Vitro Diagnostic Use.

Substantial Equivalence

Comparative performance studies conducted on 50 urine samples yielded high correlation coefficients upon comparison of the GBC Microalbumin TIA system and the predicate devices, Randox Microalbumin Test kit and Wako Micro-Albumin B. The results are summarized below:

Comparative Method	Slope	Intercept (mg/L)	Correlation Coefficient	n
Randox Microalbumin Test kit	1.20	-0.56	0.997	50
Wako Micro-Albumin B	1.20	-2.17	0.998	50

Conclusion

Good Biotech Corp. Microalbumin TIA system, calibrator set and controls are substantially equivalent to the predicate devices based on their intended purposes, design and the comparison performance results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 2 1 2005

Mr. Victor Chiou
President
Good Biotech Corp.
38, 34th Road
Taichung Industrial Park
Taichung City
Taiwan 407

Re: k050576
Trade/Device Name: Microalbumin TIA Reagent; mA1b Calibrator Set 200; mA1b Control- L, Control- H
Regulation Number: 21 CFR 866.5040
Regulation Name: Albumin immunological test system
Regulatory Class: Class II
Product Code: DDZ, JIT, JJX
Dated: March 3, 2005
Received: March 7, 2005

Dear Mr.Chiou:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050576

Device Name: Microalbumin TIA Reagent ; mAlb Calibrator Set 200 ; mAlb Control-L, Control-H

Indications For Use:

Good Biotech Corp. (GBC) Microalbumin TIA system is intended to be used for the quantitative determination of low level albumin in human **urine** by turbidimetric immunoassay (TIA). Measurement of albumin aids in the diagnosis of kidney disease.

GBC mAlb Calibrator Set 200 is intended to be used with GBC Microalbumin TIA for the quantitative determination of microalbumin in **urine** samples.

GBC Microalbumin Controls are intended to be used as the assayed quality control material for the urinary albumin analysis.

For In Vitro Diagnostic Use.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

K050576